

**AMENDMENTS TO THE CLAIMS**

The following is a complete, marked up listing of revised claims with a status identifier in parentheses, underlined text indicating insertions, and strikethrough and/or double-bracketed text indicating deletions.

LISTING OF CLAIMS

1.-9. (CANCELLED).

10. (CURRENTLY AMENDED) A method for producing a drug containing composite particle, comprising:

a primary particle formation step of forming primary particles each of which includes nano particles whose average particle diameter is less than 1000 nm; and

a combining step of combining the primary particles with each other so that the primary particles are reversibly collected, wherein a drug powder is used as the nano particles and the primary particles are subjected to secondary granulation in a fluid bed dry granulation method.

11. (ORIGINAL) The method as set forth in claim 10, wherein each of the primary particles is a nano particle clump obtained by clumping a plurality of the nano particles.

12. (PREVIOUSLY PRESENTED) The method as set forth in claim 10, further comprising a nano particle formation step of forming the nano particles by spherical crystallization.

13. (CANCELLED).

14. (PREVIOUSLY PRESENTED) The method as set forth in claim 10, wherein an average particle diameter of the primary particles is within a range of from 0.01  $\mu\text{m}$  or more to 500  $\mu\text{m}$  or less.

15. (PREVIOUSLY PRESENTED) The method as set forth in claim 10, wherein a binder is used to combine the primary particles with each other in the fluid bed dry granulation method.

16. (ORIGINAL) The method as set forth in claim 15, wherein the binder is an aqueous solution of a biocompatible polymer.

17. (PREVIOUSLY PRESENTED) The method as set forth in claim 10, wherein the combining step includes adhering the primary particles to a surface of a carrier particle using a dry mechanical particle combining method, wherein said carrier particle is larger than the primary particles in terms of an external diameter.

18. (PREVIOUSLY PRESENTED) The method as set forth in claim 17, wherein an average particle diameter of the primary particles is within a range of from 0.01  $\mu\text{m}$  or more to 500  $\mu\text{m}$  or less, and an average particle diameter of the carrier particles is within a range of from 1  $\mu\text{m}$  or more to 500  $\mu\text{m}$  or less.

19. (PREVIOUSLY PRESENTED) The method as set forth in claim 17, wherein a polysaccharide powder or a hydrophilic polymer powder is used as the carrier particle.

20. (PREVIOUSLY PRESENTED) The method as set forth in claim 17, further comprising a carrier particle surface modification step of modifying the surface of the carrier

particle, using the fluid bed dry granulation method or the dry mechanical particle combining method, before carrying out the combining step.

21. (PREVIOUSLY PRESENTED) The method as set forth in claim 20, wherein, in the carrier particle surface modification step, the surface of the carrier particle is smoothed in the fluid bed dry granulation method or the dry mechanical particle combining method, or the carrier particle is combined with lubricant particles, so as to modify the surface of the carrier particle.

22. (CANCELLED).

23. (PREVIOUSLY PRESENTED) A method for producing a drug containing composite particle, comprising:

making a mixture, containing nano particles whose average particle diameter is less than 1000 nm and a drug powder whose average particle diameter is larger than the average particle diameter of the nano particles, into a composite particle using a fluid bed dry granulation method or a dry mechanical particle combining method, so as to modify a surface of the drug powder.

24. (ORIGINAL) The method as set forth in claim 23, wherein a lubricant powder is used as the nano particles.

25. (ORIGINAL) The method as set forth in claim 24, wherein a colloidal inorganic compound powder or a surfactant powder is used as the lubricant powder.

26. (ORIGINAL) The method as set forth in claim 25, wherein the colloidal inorganic compound powder is colloidal silica.

27. (ORIGINAL) The method as set forth in claim 25, wherein the surfactant powder is magnesium stearate or sugar ester.

28. (PREVIOUSLY PRESENTED) The method as set forth in claim 24, wherein a polymer nano particle obtained by spherical crystallization is used as the lubricant powder.

29. (ORIGINAL) The method as set forth in claim 28, wherein the polymer nano particle is constituted of a lactic acid · glycolic acid copolymer or hydroxymethyl cellulose phthalate.

30. (PREVIOUSLY PRESENTED) The method as set forth in claim 23, wherein the average particle diameter of the drug powder is within a range of from 0.01  $\mu\text{m}$  or more and 500  $\mu\text{m}$  or less.

31.-36. (CANCELLED).

37. (PREVIOUSLY PRESENTED) The method as set forth in claim 11, further comprising a nano particle formation step of forming the nano particles by spherical crystallization.

38. (PREVIOUSLY PRESENTED) The method as set forth in claim 11, wherein, in the combining step, the primary particles are subjected to secondary granulation in a fluid bed dry granulation method.

39. (PREVIOUSLY PRESENTED) The method as set forth in claim 38, wherein a binder is used to combine the primary particles with each other in the fluid bed dry granulation method.

40. (PREVIOUSLY PRESENTED) The method as set forth in claim 11, wherein, the combining step included adhering the primary particles to a surface of a carrier particle using a dry mechanical particle combining method, wherein said carrier particle is larger than the primary particles in terms of an external diameter.

41. (PREVIOUSLY PRESENTED) The method as set forth in claim 18, wherein a polysaccharide powder or a hydrophilic polymer powder is used as the carrier particle.

42. (PREVIOUSLY PRESENTED) The method as set forth in claim 18, further comprising a carrier particle surface modification step of modifying the surface of the carrier particle, using a fluid bed dry granulation method or the dry mechanical particle combining method, before carrying out the combining step.

43.-44. (CANCELLED).

45. (PREVIOUSLY PRESENTED) The method as set forth in claim 24, wherein the average particle diameter of the drug powder is within a range of from 0.01  $\mu\text{m}$  or more and 500  $\mu\text{m}$  or less.

46-52. (CANCELLED).

53. (CURRENTLY AMENDED) The method as set forth in claim 10, further comprising:

preparing a casing including a cylindrical rotator that has a vertical axis provided at a center of the casing and has a receiving face ~~directing~~facing the center, the casing including a press head that has the same vertical axis and ~~directs~~faces the receiving face of the cylindrical rotator;

putting the mixture into the casing;

rotating at least one of the receiving face and the press head around the vertical axis; and

giving a pressure and a shearing force to the mixture located at a press section between the press head and the receiving face by rotating at least one of the receiving face and the press head around the vertical axis so as to combine the powder materials with each other.

54. (PREVIOUSLY PRESENTED) The method as set forth in claim 53, wherein a horizontal cross-sectional surface of the press head is semi-circular.

55. (PREVIOUSLY PRESENTED) The method as set forth in claim 54, wherein a curvature of the press head is higher than a curvature of the receiving face.

56. (PREVIOUSLY PRESENTED) The method as set forth in claim 23, further comprising:

preparing a casing including a cylindrical rotator that has a vertical axis provided at a center of the casing and has a receiving face directing the center, the casing including a press head that has the same vertical axis and directs the receiving face of the cylindrical rotator;

putting the mixture into the casing;

rotating at least one of the receiving face and the press head around the vertical axis; and

giving a pressure and a shearing force to the mixture located at a press section between the press head and the receiving face by rotating at least one of the receiving face and the press head around the vertical axis so as to combine the powder materials with each other.

57. (PREVIOUSLY PRESENTED) The method as set forth in claim 56, wherein a horizontal cross-sectional surface of the press head is semi-circular.

58. (PREVIOUSLY PRESENTED) The method as set forth in claim 57, wherein a curvature of the press head is higher than a curvature of the receiving face.

59. (CURRENTLY AMENDED) A method for producing a drug containing composite particle containing a drug and a biocompatible polymer, wherein the drug is a particle having a particle diameter and the biocompatible polymer is a particle having a particle diameter, comprising the steps of:

making at least one of the drug and the biocompatible polymer into a nano particle having an average particle diameter less than 1000 nm;

a primary particle formation step of forming a primary particle comprising a nano particle clump containing the nano particle; and

a combining step of combining a first primary particle and a second primary particle with each other so that the first and second primary particles are reversibly collected, so as to form a polymer nano composite particle, wherein the first and second primary particles are combined with each other using a fluid bed dry granulation method.

60. (PREVIOUSLY PRESENTED) The method as set forth in claim 59,

wherein the drug is a nano particle and the biocompatible polymer is not a nano particle,

the particle diameter of the biocompatible polymer is larger than the particle diameter of each of the primary particles, and

in the combining step, the primary particles are combined with each other by using the biocompatible polymer as a binder.

61. (PREVIOUSLY PRESENTED) The method as set forth in claim 59,

wherein the drug is a nano particle and the biocompatible polymer is not a nano particle,

the particle diameter of the biocompatible polymer is larger than particle diameter of each of the primary particles,

in the combining step, the primary particles are made to adhere to a surface of each of the biocompatible polymer particles as carrier particles.

62. (CURRENTLY AMENDED) A method for producing a drug containing composite particle containing a drug and a biocompatible polymer, wherein the drug is a particle having a particle diameter and the biocompatible polymer is a particle having a particle diameter, comprising the steps of:

making at least one of the drug and the biocompatible polymer into a nano particle having an average particle diameter less than 1000 nm;

a primary particle formation step of forming a primary particle comprising a nano particle clump containing the nano particle; and

a combining step of combining a first primary particle and a second primary particle with each other so that the first and second primary particles are reversibly



collected, so as to form a polymer nano composite particle~~The method as set forth in claim 59,~~

wherein both the drug and the biocompatible polymer are nano particles,

the method further comprising, before carrying out the combining step, a carrier surface modification step of modifying a surface of a carrier particle by combining the carrier particle and the biocompatible polymer, wherein the biocompatible polymer is a lubricant particle and the carrier particles have a particle diameter larger than a particle diameter of the primary particles, and

in the combining step, the primary particles are made to adhere to a surface of each of the modified carrier particles.

63. (CANCELLED).

64. (CURRENTLY AMENDED) The method as set forth in claim 59,

wherein in the combining step, the primary particles are combined with each other using a dry mechanical particle ~~combing~~ combining method.

65. (NEW) A method for producing a drug containing composite particle, comprising:

a primary particle formation step of forming primary particles each of which includes nano particles whose average particle diameter is less than 1000 nm;

a combining step of combining the primary particles with each other so that the primary particles are reversibly collected, wherein a drug powder is used as the nano particles; and

a carrier particle surface modification step of modifying the surface of the carrier particle, using the fluid bed dry granulation method or the dry mechanical particle combining method, before carrying out the combining step.

66. (NEW) A method for producing a drug containing composite particle containing a drug and a biocompatible polymer, wherein the drug is a particle having a particle diameter and the biocompatible polymer is a particle having a particle diameter, comprising the steps of:

making at least one of the drug and the biocompatible polymer into a nano particle having an average particle diameter less than 1000 nm;

a primary particle formation step of forming a primary particle comprising a nano particle clump containing the nano particle;

a combining step of combining a first primary particle and a second primary particle with each other so that the first and second primary particles are reversibly collected, so as to form a polymer nano composite particle; and

a carrier particle surface modification step of modifying the surface of the carrier particle, using the fluid bed dry granulation method or the dry mechanical particle combining method, before carrying out the combining step.